

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA,
Plaintiff,

v.

DR. ELIZABETH N. KUH,
Defendant.

Civil Action No.

COMPLAINT

Dr. Elizabeth Kuh was a board-certified psychiatrist who had no specialization or training in pain management, but who repeatedly prescribed a husband-and-wife couple 80mg OxyContin and other controlled substances. The prescriptions were issued to the couple frequently by mail without an in-person physical examination, without urine drug screens or diagnostic testing, frequently not recorded in Kuh's records, and frequently while the wife's pain management and other conditions were managed by other providers. Kuh's improper prescribing continued for years, despite the potential adverse mental health consequences to the wife.

The prescribing only ended after the husband committed suicide. Kuh had sent prescriptions of OxyContin through the mail to the husband—once again, without physical examination or attempting alternative treatments.

Kuh's opioid prescribing to the couple lacked a legitimate medical purpose, was outside the usual course of professional practice, and resulted in false claims to Medicare. The United States brings this suit to address Kuh's improper controlled substance prescribing.

PARTIES

1. Plaintiff is the United States of America.

2. Defendant Elizabeth N. Kuh, M.D., is a Pennsylvania resident. During the allegations in this complaint, Kuh was licensed to practice medicine in Pennsylvania and practiced in Montgomery County, Pennsylvania.

JURISDICTION AND VENUE

3. This action is brought by the United States for civil penalties and injunctive relief under the Controlled Substances Act, 21 U.S.C. §§ 801-971, and for civil damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729-33.

4. This Court has subject matter jurisdiction over the alleged Controlled Substances Act civil penalties, 21 U.S.C. § 842, pursuant to 21 U.S.C. § 842(c)(1)(A), and 28 U.S.C. §§ 1331, 1345, and 1355.

5. This Court has subject matter jurisdiction over the alleged Controlled Substances Act injunctive relief, 21 U.S.C. §§ 843(f), 882, pursuant to 21 U.S.C. §§ 843(f), 882, and 28 U.S.C. §§ 1331, 1345.

6. This Court has subject matter jurisdiction over the alleged False Claims Act counts, 31 U.S.C. § 3729, pursuant to 31 U.S.C. § 3732(a), and 28 U.S.C. §§ 1331, 1345, and 1355.

7. This Court has personal jurisdiction over Defendant Kuh because she resides in, is located in, transacted business in, and committed the acts at issue in this district.

8. Venue is proper in the Eastern District of Pennsylvania under 28 U.S.C. §§ 1391, 1395, and 31 U.S.C. § 3732(a) because defendant is located, resides, did business, and a substantial part of the events or omissions giving rise to the claims occurred in this district.

REGULATORY BACKGROUND

I. The Controlled Substances Act

9. The Controlled Substances Act (CSA), 21 U.S.C. § 801 *et seq.*, and its regulations govern prescription writing by practitioners for controlled substances. The CSA establishes strict guidelines “to ensure a sufficient supply for legitimate medical . . . purposes and to deter diversion of controlled substances to illegal purposes. The substances are regulated because of their potential for abuse and likelihood to cause dependence when abused and because of their serious and potentially unsafe nature if not used under proper circumstances.” 75 Fed. Reg. 61613 (Oct. 6, 2010).

10. Federal legislation dictates how prescriptions drugs are categorized. Drugs can be placed in Schedules I through V based on, *inter alia*, their “potential for abuse” and whether they have “a currently accepted medical use in treatment.” 21 U.S.C. § 812(b)(2). Schedule II controlled substances are those that have a “high potential for abuse” that “may lead to severe psychological or physical dependence,” but have “a currently accepted medical use in treatment.” *Id.*

11. Pursuant to legislation and administrative action by the Drug Enforcement Administration:

- a. oxycodone (with brand names including OxyContin) is an opioid categorized as a Schedule II controlled substance, *see* 21 C.F.R. § 1308.12,
- b. lorazepam (with brand names including Ativan) is a benzodiazepine categorized as a Schedule IV controlled substance, *see* 21 C.F.R. § 1308.14, and

- c. temazepam (with brand names including Restoril) is a benzodiazepine categorized as a Schedule IV controlled substance, *see* 21 C.F.R. § 1308.14.

12. The CSA requires those who manufacture, distribute, or dispense controlled substances, including doctors who write prescriptions for those drugs, to obtain a registration from the Drug Enforcement Administration. 21 U.S.C. § 822(a). However, a registrant may only distribute or dispense a controlled substance as “authorized by their registration and in conformity with the other provisions of” the CSA. *Id.* § 822(b).

13. Unless dispensed directly or in an emergency, no Schedule II controlled substance may be dispensed without the written prescription of a practitioner, such as a physician. 21 U.S.C. § 829(a). Unless dispensed directly, Schedule III and IV controlled substances also require an effective written or oral prescription. *Id.* § 829(b).

14. A prescription for purposes of the CSA is only effective if issued for a *legitimate medical purpose* by an individual practitioner *acting in the usual course of his professional practice*. . . . An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and . . . the person issuing [such a purported prescription], shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

21 C.F.R. § 1306.04(a) (emphasis added).

15. In addition, the CSA’s regulations require that a prescription for a controlled substance “be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner.” *Id.* § 1306.05(a).

16. The responsibility for proper prescribing and dispensing of these drugs rests with the prescribing practitioner. *Id.* § 1306.04(a).

II. Pennsylvania Standards for Controlled Substance Prescribing

17. The Commonwealth of Pennsylvania imposes a number of additional requirements and standards for physicians who prescribe controlled substances.

18. For example, 49 Pa. Code § 16.92 governs prescribing of controlled substances.

19. Section 16.92 provides that, when physicians write a prescription for a controlled substance, there must be an initial medical history and physical examination, absent an emergency. “The physical examination shall include an objective evaluation of the heart, lungs, blood pressure and body functions that relate to the patient’s specific complaint.”

20. Section 16.92 also calls for

- a. reevaluations “consistent with the condition diagnosed, the drug or drugs involved, expected results and possible side effects”;
- b. counseling “about dosage levels, instructions for use, frequency and duration of use and possible side effects”; and
- c. “[a]ccurate and complete medical records” that “document the evaluation and care received by patients,” including the drug prescribed and the symptoms, diagnosis, and directions upon the initial prescription.

III. The Medicare Part D Program

21. Medicare is a federal program administered by the Centers for Medicare & Medicaid Services (CMS), a federal agency within the U.S. Department of Health and Human Services, to pay for the costs of certain health care services provided to eligible individuals. Individual entitlement to Medicare is largely based on age, disability, or affliction with end-stage renal disease. 42 U.S.C. §§ 426, 426-1.

22. One piece of the Medicare program is Medicare Part D, which covers the costs of certain prescription drugs for Medicare beneficiaries. 42 U.S.C. § 1395w-101(a)(3)(A); 42 C.F.R. § 423.30(a).

23. Medicare provides Part D coverage through plan “sponsors,” which are private entities that administer the prescription drug plans on behalf of the federal government.

24. Part D plan sponsors provide reimbursement to pharmacies for drugs, such as oxycodone, lorazepam, and temazepam, dispensed to Medicare beneficiaries enrolled in Part D.

25. Claims submitted for these drugs are recorded and sent to CMS through a prescription drug event (PDE) record, which contains information about the drug dispensed, the beneficiary, the practitioner who prescribed the drug, and payment.

26. CMS makes payments to reimburse the sponsors through (a) monthly estimated payments based upon the beneficiaries enrolled; (b) cost-sharing subsidies for low-income individuals; and (c) payments made annually that reconcile the estimated monthly payments with the allowable costs the sponsor actually incurred. The PDE records are a significant factor influencing the reimbursement amounts.

27. Part D plan sponsors repeatedly certify their compliance with applicable federal laws, regulations, and CMS guidance and certify to the accuracy and truthfulness of the data in the PDE records as a condition of payment.

28. Medicare only covers drugs that are for a medically accepted indication, which is approved under the Food, Drug, and Cosmetic Act, or as supported in one of the listed compendia. 42 U.S.C. §§ 1395w-102(e), 1396r-8(g)(1)(B) & (k)(6); 42 C.F.R. § 423.100. Any drugs that do not comply with this requirement render the PDE inaccurate, incomplete, and/or untruthful.

29. If prescriptions are issued for something other than a medically accepted indication, they are not covered by Part D. 42 U.S.C. §§ 1395w-102(e), 1396r-8(k)(6).

30. In addition, Part D plan sponsors are only permitted to provide benefits for Part D drugs “that require a prescription if those drugs are dispensed upon a valid prescription.” 42 C.F.R. § 423.104(h). A prescription is only valid if it “complies with all applicable State law requirements constituting a valid prescription.” 42 C.F.R. § 423.100.

FACTS

I. Background of Defendant Elizabeth Kuh

31. Defendant Elizabeth Kuh attended Boston University School of Medicine and graduated in 1985. She completed a psychiatry residency and a two-year fellowship in child and adolescent psychiatry. She has been licensed to practice medicine in Pennsylvania since 1986.

32. Kuh had obtained a registration with the DEA to prescribe controlled substances and was subject to the CSA’s requirements at all times relevant to this complaint.

33. Kuh was board-certified in psychiatry, from 1992 through 2018.

34. Kuh is not a pain management physician and was never board-certified in pain management.

35. Kuh practiced as a community-based psychiatrist in Montgomery County, Pennsylvania since approximately 1990.

II. Kuh Started Seeing Patient J.W. in the 1990s for Depression and Anxiety

36. Defendant Kuh started seeing patient J.W. in 1994 “for relatively straightforward issues of depression and anxiety.”

37. Kuh treated J.W.’s depression with Prozac as of October 1994 and “saw her on a regular basis for supportive therapy.”

38. The medical records for the first-recorded visit in 1994 also reflect physical ailments for J.W., along with a recognition that other providers were treating those conditions.

39. While Kuh took lengthy notes on J.W.'s mental health during this first recorded encounter, she did not conduct a physical examination or take J.W.'s vitals.

40. Kuh never conducted a physical examination of J.W. or J.W.'s husband, G.W.

41. Kuh continued to treat J.W. for these mental health issues through the 1990s and 2000s.

III. Kuh Prescribed Controlled Substances to J.W. and G.W., Including Opioids to J.W. for Pain, and J.W.'s Mental Health Deteriorated

42. Records indicate that J.W.'s physical conditions and symptoms, particularly her pain, became more serious problems starting around 2009.

43. Sometime in 2009, Kuh, without any training or specialization in pain management, and without ever conducting a physical examination or taking vitals, wrote opioid prescriptions to J.W., including fentanyl.

44. It appears that Kuh started sending at least some prescriptions through the mail without seeing J.W. at the time of issuing the prescription and post-dating the prescriptions.

45. J.W. had been seen and cared for by a number of different providers for her physical conditions and symptoms, and at least one provider started to be concerned with J.W.'s use of pain medication and signs of addiction.

46. As of July 2009, Kuh's opioid prescriptions were already causing adverse health consequences for J.W.

47. Kuh's prescriptions for opioid pain medications increased in 2011, when Kuh began prescribing J.W. 80mg OxyContin, which would continue for years. Kuh's OxyContin

prescriptions for J.W. were filled 43 different times from 2011 through 2014, for a total of over 5,600 pills of OxyContin. She also prescribed benzodiazepines from June 2011 through 2014.

48. The combination of opioid and benzodiazepine prescriptions significantly increases the risk of respiratory arrest and death.

49. In the midst of Kuh's opioid prescribing, insurance companies started expressing warnings. For example, J.W.'s insurer sent warnings with a narcotic drug utilization review that asked Kuh to evaluate the monthly prescriptions for 80mg OxyContin, filled on October 12, 2011, November 10, 2011, December 2, 2011, and December 31, 2011, for a total of 420 pills. There is nothing in her records to indicate she did anything in response to the review.

50. Kuh's record from June 2011 also raised concerns about the propriety of the opioid prescribing to J.W., with Kuh writing in June 2011: "Narcotics don't help the pain that much, 'relief from reality.'"

51. That same month, J.W.'s mental condition worsened, with a letter from G.W. to Kuh indicating that J.W. was in a state of "mental decline."

52. In February 2012, G.W. expressed his own mental health issues to Kuh as a result of J.W.'s condition, expressing thoughts of suicide for the first time: "I would end my life if it weren't so cowardly."

53. There is nothing in the record indicating that Defendant Kuh did anything in response to this reference to suicide.

54. Kuh began prescribing controlled substances to J.W.'s husband, G.W., including the benzodiazepine lorazepam, in 2011.

55. G.W. himself started to show signs of drug abuse. For example, he violated another provider's directions with respect to using a synthetic opioid pain medication.

IV. Starting in 2014, J.W. Began Hallucinating, and Independent Providers Considered that the Kuh Opioids May Have Contributed to Her Mental Issues

56. J.W.'s mental health condition deteriorated in 2014. J.W. began having difficulty staying awake and experienced hallucinations, including seeing animals in the plumbing in her home. Kuh was aware of the hallucinations.

57. J.W.'s behavior included a number of warning signs of addiction, and another provider diagnosed J.W. with polydrug habituation, including for opioids and benzodiazepines.

58. On several different occasions, providers expressed concern about Kuh's opioid prescribing and its potential for contributing or causing these hallucinations, and Kuh was aware of at least some of those concerns.

59. Despite the request by another provider to reduce the OxyContin prescribing and despite G.W. expressing concerns that J.W.'s medications were the cause of the behavior, J.W. continued to fill OxyContin prescriptions written by Defendant Kuh through January 2016.

60. Insurers continued to submit warnings to Kuh about the OxyContin prescriptions, with letters sent in May 2014, August 2014, December 2014, February 2015, April 2015, July 2015, October 2015, and February 2016.

61. In many cases, Defendant Kuh did not even note in her records that she had prescribed temazepam or 80mg OxyContin to J.W.

62. With respect to J.W., Kuh never performed a physical examination or took vitals and never performed urine drug screens.

V. Kuh Prescribed OxyContin and Benzodiazepines to G.W., Who Ultimately Committed Suicide

63. Around May 2014, Kuh began prescribing G.W. his own OxyContin, when G.W. claimed he had a torn "stomach muscle."

64. G.W. filled his first 80mg OxyContin prescription from Kuh on May 27, 2014, and he was brought to the emergency room two days later, on May 29, 2014, with a diagnosis of “Adverse Drug Reaction” and “Fall” as a result of not taking the OxyContin as prescribed.

65. Kuh continued to prescribe G.W. OxyContin after this incident. Between March 2014 and December 2015, G.W. filled a number of prescriptions written by Kuh for 80mg OxyContin and the benzodiazepine lorazepam.

66. In many cases, Defendant Kuh did not note in her records that she had prescribed the drugs to G.W., and there is frequently no medical record at all for G.W.

67. Kuh never performed an appropriate history and physical examination of G.W., never reviewed or ordered diagnostic tests, never screened him for abuse and aberrant behavior, never prescribed non-opioid pain therapy, and did not start with a low-dose opioid therapy.

68. G.W. had already mentioned suicide and his death in letters to Kuh while caring for his wife.

69. G.W.’s mental health issues became more pronounced, and those issues were disclosed in notes to or by Kuh.

70. G.W. committed suicide on January 10, 2016.

71. G.W. left a suicide note for his wife and family, in which he wrote: “I am a drunk & a pill addict.”

72. With only two exceptions, the only controlled substances that G.W. had filled after February 2015 were prescribed by Defendant Kuh.

73. In distress from her husband’s suicide, one of J.W.’s first acts after the suicide was to call Defendant Kuh and ask for a refill on her OxyContin.

74. Kuh sent J.W. seven additional prescriptions for 80mg OxyContin, dating them as January 11, 2016, January 12, 2016, January 13, 2016, February 10, 2016, February 12, 2016, March 13, 2016, and April 12, 2016—all without examining J.W.

**COUNTS 1—30:
Unlawful Distributing and Dispensing of Controlled Substances:
21 U.S.C. §§ 842(a)(1), 829**

75. The United States realleges the above paragraphs as if fully set forth herein.

76. Defendant Kuh is subject to the requirements of Part C of the CSA, 21 U.S.C. § 822.

77. As alleged above, Kuh wrote prescriptions for, and therefore distributed and/or dispensed, controlled substances without a legitimate medical purpose and outside the usual course of professional practice, in violation of 21 U.S.C. § 829(a), (b) and 21 C.F.R. § 1306.04.

78. Several of Kuh's prescriptions also violated 21 U.S.C. § 829(a), (b) and 21 C.F.R. § 1306.05, in that the prescriptions were post-dated and did not contain the address of the patient.

79. Kuh wrote prescriptions for, and patients J.W. and G.W. filled, the following controlled substance prescriptions, in violation of the CSA:

<i>Violation #</i>	<i>Date Filled</i>	<i>Pharmacy</i>	<i>Patient</i>	<i>Drug</i>	<i>Qty</i>
1	7/27/2014	SavOn	J.W.	OXYCONTIN 80MG TABLET	150
2	8/26/2014	SavOn	J.W.	OXYCONTIN 80MG TABLET	150
3	9/24/2014	SavOn	J.W.	OXYCONTIN 80MG TABLET	150
4	10/14/2014	SavOn	J.W.	TEMAZEPAM 30MG CAPSULE	30
5	10/23/2014	SavOn	J.W.	OXYCONTIN 80MG TABLET	150
6	11/18/2014	SavOn	G.W.	OXYCONTIN 80MG TABLET	90
7	11/22/2014	SavOn	J.W.	OXYCONTIN 80MG TABLET	150

8	12/5/2014	SavOn	G.W.	LORAZEPAM 2MG TABLET	30
9	12/17/2014	SavOn	G.W.	OXYCONTIN 80MG TABLET	90
10	12/21/2014	SavOn	J.W.	OXYCONTIN 80MG TABLET	150
11	1/19/2015	SavOn	J.W.	OXYCONTIN 80MG TABLET	150
12	2/12/2015	SavOn	G.W.	OXYCONTIN 80MG TABLET	60
13	2/18/2015	SavOn	J.W.	OXYCONTIN 80MG TABLET	120
14	3/7/2015	SavOn	G.W.	LORAZEPAM 2MG TABLET	30
15	3/19/2015	SavOn	J.W.	OXYCONTIN 80MG TABLET	100
16	3/30/2015	SavOn	G.W.	LORAZEPAM 2MG TABLET	30
17	4/17/2015	SavOn	J.W.	OXYCONTIN 80MG TABLET	120
18	5/17/2015	SavOn	J.W.	OXYCONTIN 80MG TABLET	120
19	6/1/2015	SavOn	G.W.	LORAZEPAM 2MG TABLET	30
20	6/16/2015	SavOn	J.W.	OXYCONTIN 80MG TABLET	120
21	7/16/2015	SavOn	J.W.	OXYCONTIN 80MG TABLET	120
22	8/15/2015	SavOn	J.W.	OXYCONTIN 80MG TABLET	120
23	9/15/2015	SavOn	J.W.	OXYCONTIN 80MG TABLET	120
24	10/12/2015	SavOn	G.W.	LORAZEPAM 2MG TABLET	30
25	10/14/2015	SavOn	J.W.	OXYCONTIN 80MG TABLET	120
26	11/13/2015	SavOn	J.W.	OXYCONTIN 80MG TABLET	120
27	12/12/2015	CVS	G.W.	LORAZEPAM 2 MG TABLET	30
28	12/12/2015	CVS	J.W.	OXYCONTIN 80 MG TABLET	120
29	1/12/2016	CVS	J.W.	OXYCONTIN 80 MG TABLET	8
30	1/15/2016	CVS	J.W.	OXYCONTIN 80 MG TABLET	120

80. As a result of the violations set forth above, Defendant Kuh is subject to the relief set forth in the CSA.

COUNTS 31—58:
Causing the Presentation of False Claims:
31 U.S.C. § 3729(a)(1)(A)

81. The United States realleges the above paragraphs as if fully set forth herein.

82. Defendant Kuh, due to her repeatedly signing prescriptions for Schedule II and IV controlled substances without a medically accepted indication or medical necessity, and failing to comply with State law, filled and paid for by Medicare Part D, knowingly caused the presentation of false and fraudulent claims for payment or approval to Medicare, in violation of 31 U.S.C. § 3729(a)(1)(A), upon the pharmacies' submission of their claims to Medicare.

<i>Violation #</i>	<i>Date Filled</i>	<i>Pharmacy</i>	<i>Patient</i>	<i>Drug</i>	<i>Qty</i>
31	7/27/2014	SavOn	J.W.	OXYCONTIN 80MG TABLET	150
32	8/26/2014	SavOn	J.W.	OXYCONTIN 80MG TABLET	150
33	9/24/2014	SavOn	J.W.	OXYCONTIN 80MG TABLET	150
34	10/14/2014	SavOn	J.W.	TEMAZEPAM 30MG CAPSULE	30
35	10/23/2014	SavOn	J.W.	OXYCONTIN 80MG TABLET	150
36	11/22/2014	SavOn	J.W.	OXYCONTIN 80MG TABLET	150
37	12/5/2014	SavOn	G.W.	LORAZEPAM 2MG TABLET	30
38	12/21/2014	SavOn	J.W.	OXYCONTIN 80MG TABLET	150
39	1/19/2015	SavOn	J.W.	OXYCONTIN 80MG TABLET	150
40	2/18/2015	SavOn	J.W.	OXYCONTIN 80MG TABLET	120
41	3/7/2015	SavOn	G.W.	LORAZEPAM 2MG TABLET	30
42	3/19/2015	SavOn	J.W.	OXYCONTIN 80MG TABLET	100
43	3/30/2015	SavOn	G.W.	LORAZEPAM 2MG TABLET	30
44	4/17/2015	SavOn	J.W.	OXYCONTIN 80MG TABLET	120
45	5/17/2015	SavOn	J.W.	OXYCONTIN 80MG TABLET	120

46	6/1/2015	SavOn	G.W.	LORAZEPAM 2MG TABLET	30
47	6/16/2015	SavOn	J.W.	OXYCONTIN 80MG TABLET	120
48	7/16/2015	SavOn	J.W.	OXYCONTIN 80MG TABLET	120
49	8/15/2015	SavOn	J.W.	OXYCONTIN 80MG TABLET	120
50	9/15/2015	SavOn	J.W.	OXYCONTIN 80MG TABLET	120
51	10/12/2015	SavOn	G.W.	LORAZEPAM 2MG TABLET	30
52	10/14/2015	SavOn	J.W.	OXYCONTIN 80MG TABLET	120
53	11/12/2015	SavOn	G.W.	LORAZEPAM 2MG TABLET	30
54	11/13/2015	SavOn	J.W.	OXYCONTIN 80MG TABLET	120
55	12/12/2015	CVS	G.W.	LORAZEPAM 2 MG TABLET	30
56	12/12/2015	CVS	J.W.	OXYCONTIN 80 MG TABLET	120
57	1/12/2016	CVS	J.W.	OXYCONTIN 80 MG TABLET	8
58	1/15/2016	CVS	J.W.	OXYCONTIN 80 MG TABLET	120

83. By virtue of these false and/or fraudulent claims, the United States has suffered damages and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty for each false claim submitted.

PRAYER FOR RELIEF

WHEREFORE, the United States of America demands judgment against defendant Elizabeth Kuh as follows:

1. Civil penalties of up to \$25,000 per violation occurring on or before November 2, 2015, 21 U.S.C. § 842(c)(1)(A); civil penalties of up to \$64,820 per violation occurring after November 2, 2015, 28 C.F.R. § 85.5;

2. Injunctive relief, pursuant to 21 U.S.C. §§ 843(f), 882, permanently enjoining Kuh from prescribing controlled substances, as defined by the Controlled Substances Act, 21 U.S.C. §§ 801 *et seq.*, and its implementing regulations;

3. Damages sustained by the United States, trebled, as mandated by 31 U.S.C. § 3729(a)(1);

4. Civil penalties of between \$5,500 and \$11,000 for each false claim presented on or before November 2, 2015, 31 U.S.C. § 3729(a)(1); 28 C.F.R. § 85.3(a)(9); civil penalties of between \$11,181 and \$22,363 for each false claim presented after November 2, 2015, 28 C.F.R. § 85.5; and

5. Post-judgment interest, costs, and such other and further relief as the Court deems just and equitable.

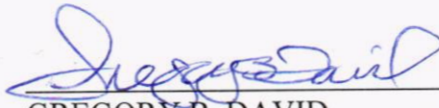
JURY DEMAND

The United States hereby demands a trial by jury of all issues so triable pursuant to Rule 38 of the Federal Rules of Civil Procedure.

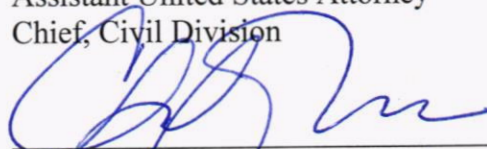
Respectfully submitted,



WILLIAM M. McSWAIN
United States Attorney



GREGORY B. DAVID
Assistant United States Attorney
Chief, Civil Division



CHARLENE KELLER FULLMER
Assistant United States Attorney
Deputy Chief, Civil Division



ANTHONY D. SCICCHITANO
Assistant United States Attorney
PA 208607
United States Attorney's Office
615 Chestnut Street, Suite 1250
Philadelphia, PA 19106
(215) 861-8380
anthony.scicchitano@usdoj.gov

*Attorneys for the
United States of America*

Dated: August 7, 2019

JS 44 (Rev. 06/17)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

United States of America

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)
AUSA Anthony D. Scicchitano
U.S. Attorney's Office, 615 Chestnut Street, Suite 1250
Philadelphia, PA 19106 (215) 861-8380

DEFENDANTS

Dr. Elizabeth N. Kuh

County of Residence of First Listed Defendant Philadelphia County
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)
James J. Kutz, Esquire
Post & Schell, P.C., 17 N. Second Street, 12th Floor
Harrisburg, PA 17101 (717) 612-6038

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☒ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- | | PTF | DEF | | PTF | DEF |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| Citizen of This State | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	PERSONAL INJURY <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other	<input checked="" type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 490 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	PRISONER PETITIONS Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other	PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark
		LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157	SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g))
		IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	

V. ORIGIN (Place an "X" in One Box Only)

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from Another District (specify)
- ☐ 6 Multidistrict Litigation - Transfer
- ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):

31 U.S.C. § 3729, 21 U.S.C. § 842

Brief description of cause:

False Claims Act, Controlled Substance Act

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$ _____

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No**VIII. RELATED CASE(S) IF ANY**

(See instructions):

JUDGE _____

DOCKET NUMBER _____

DATE

08/05/2019

SIGNATURE OF ATTORNEY OF RECORD

AUSA Anthony D. Scicchitano

FOR OFFICE USE ONLY

RECEIPT # _____

AMOUNT _____

APPLYING IFP _____

JUDGE _____

MAG. JUDGE _____

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

DESIGNATION FORM

(to be used by counsel or pro se plaintiff to indicate the category of the case for the purpose of assignment to the appropriate calendar)

Address of Plaintiff: 615 Chestnut Street, Suite 1250, Philadelphia, PA 19106

Address of Defendant: Wyndmoor, PA

Place of Accident, Incident or Transaction: Montgomery County, PA

RELATED CASE, IF ANY:

Case Number: N/A Judge: _____ Date Terminated: _____

Civil cases are deemed related when **Yes** is answered to any of the following questions:

- | | | |
|--|------------------------------|--|
| 1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| 2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| 3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action of this court? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| 4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |

I certify that, to my knowledge, the within case ☐ is / ☒ is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: _____ Attorney-at-Law / Pro Se Plaintiff _____ Attorney I.D. # (if applicable) _____

CIVIL: (Place a ☒ in one category only)

A. Federal Question Cases:

- ☐ 1. Indemnity Contract, Marine Contract, and All Other Contracts
- ☐ 2. FELA
- ☐ 3. Jones Act-Personal Injury
- ☐ 4. Antitrust
- ☐ 5. Patent
- ☐ 6. Labor-Management Relations
- ☐ 7. Civil Rights
- ☐ 8. Habeas Corpus
- ☐ 9. Securities Act(s) Cases
- ☐ 10. Social Security Review Cases
- ☒ 11. All other Federal Question Cases
(Please specify): False Claims Act, Controlled Substance Act

B. Diversity Jurisdiction Cases:

- ☐ 1. Insurance Contract and Other Contracts
- ☐ 2. Airplane Personal Injury
- ☐ 3. Assault, Defamation
- ☐ 4. Marine Personal Injury
- ☐ 5. Motor Vehicle Personal Injury
- ☐ 6. Other Personal Injury (Please specify): _____
- ☐ 7. Products Liability
- ☐ 8. Products Liability - Asbestos
- ☐ 9. All other Diversity Cases
(Please specify): _____

ARBITRATION CERTIFICATION

(The effect of this certification is to remove the case from eligibility for arbitration.)

I, Anthony D. Scicchitano, counsel of record or pro se plaintiff, do hereby certify:

- ☐ Pursuant to Local Civil Rule 53.2, § 3(c) (2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of \$150,000.00 exclusive of interest and costs:
- ☒ Relief other than monetary damages is sought.

DATE: 08/05/2019 Anthony D. Scicchitano Attorney-at-Law / Pro Se Plaintiff 208607 Attorney I.D. # (if applicable)

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

CASE MANAGEMENT TRACK DESIGNATION FORM

UNITED STATES OF AMERICA
Plaintiff,

v.

DR. ELIZABETH N. KUH,
Defendant.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

- (a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ()
- (b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ()
- (c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ()
- (d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ()
- (e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) ()
- (f) Standard Management – Cases that do not fall into any one of the other tracks. (X)

8/5/2019
Date

Anthony D. Scicchitano, Attorney-at-law

Plaintiff United States of America
Attorney for

215.861.8380
Telephone
(Civ. 660) 10/02

215.861.8618
Fax Number

anthony.scicchitano@usdoj.gov
E-Mail Address